This document is scheduled to be published in the

DEPARTMENT STATE ALTH AND 12/2014 and available online at

nttp://federalregister.gov/a/2014-05328, and on FDsys.gov

Centers for Medicare & Medicaid Services

[CMS-3286-FN]

Medicare and Medicaid Programs; Application from the Joint Commission for Continued Approval of its Home Health Agency (HHA) Accreditation Program.

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Final Notice.

SUMMARY: This notice announces our decision to approve the Joint Commission for continued recognition as a national accreditation program for Home Health Agencies (HHAs) seeking to participate in the Medicare or Medicaid programs. An HHA that participates in Medicaid must, in accordance with §440.70(d) meet the Medicare participation requirements, and may demonstrate compliance through deemed status, as provided for under §488.6(b), with the exception of the capitalization requirements at §489.28.

EFFECTIVE DATE: This final notice is effective March 31, 2014 through March 31, 2020.

FOR FURTHER INFORMATION CONTACT:

Lillian Williams, (410) 786-8636, Patricia Chmielewski, (410) 786-6899, or Monda Shaver, (410) 786-3410.

SUPPLEMENTAL INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a HHA provided certain requirements are met. Sections 1861(o) and 1891 of the Social Security Act (the Act), establish distinct criteria for facilities seeking to participate in Medicare as an HHA. Regulations concerning Medicare provider agreements are at part 489 and those pertaining to activities relating to the survey and certification of facilities are at part 488. The regulations at part 484 specify the minimum conditions that a HHA must meet to be certified to participate in the Medicare program.

Generally, to enter into a Medicare agreement, a HHA must first be certified by a state survey agency as complying with the conditions set forth in part 484 of the Medicare regulations. Thereafter, the HHA is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. There is an alternative, however, to surveys by State agencies.

Section 1865(a) of the Act provides that, if an accrediting organization is recognized by the Secretary as having standards for accreditation that meet or exceed all applicable Medicare conditions or requirements, as well as comparable survey procedures, a provider entity accredited under the national accrediting body's approved Medicare accreditation program would be deemed to meet the Medicare conditions or requirements. Accreditation under an approved Medicare accreditation program of an accrediting organization is voluntary and is not required for Medicare participation.

A national accrediting organization applying for approval of its accreditation program in accordance with section 1865(a)(2) and (3) of the Act and our implementing regulations at part 488, subpart A, must provide us with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as all of the applicable Medicare conditions or requirements. Our regulations concerning the approval of accrediting organizations are set forth at §488.4 and §488.8(d)(3). The regulations at §488.8(d)(3) require accrediting organizations to reapply for continued approval of a Medicare accreditation program every 6 years or sooner, as determined by us.

The Joint Commission's current term of approval for its HHA accreditation program expires March 31, 2014.

II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at §488.8(a) require that our findings concerning review and approval of a national accrediting organization's requirements consider,

among other factors, the applying accrediting organization's requirements for accreditation; its survey procedures; its ability to provide adequate resources for conducting required surveys and to furnish us information for use in enforcement activities; its monitoring procedures for provider entities found not in compliance with the conditions or requirements; and its ability to provide us with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

III. Proposed Notice

On October 25, 2013, we published a proposed notice (78 FR 63984) announcing the Joint Commission's request for re-approval of its Medicare accreditation program for HHAs. In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and our regulations at §488.4 (Application and reapplication procedures for accreditation organizations), we conducted a review of the Joint Commission's application in accordance with the criteria specified by our regulation, which include, but are not limited to the following:

- An onsite administrative review of the Joint Commission's: (1) corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and (5) survey review and decision-making process for accreditation.
- A comparison of the Joint Commission's HHA accreditation standards to our current
 Medicare HHA conditions of participation.
 - A documentation review of the Joint Commission's survey processes to:

- ++ Determine the composition of the survey team, surveyor qualifications, and the ability of the Joint Commission to provide continuing surveyor training.
- ++ Compare the Joint Commission's processes to those we require of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.
- ++ Evaluate the Joint Commission's procedures for monitoring providers or suppliers found to be out of compliance with the Joint Commission HHA program requirements. The monitoring procedures are required only when the Joint Commission identifies noncompliance. If substantial noncompliance is identified through a state validation survey, the state survey agency monitors corrections as specified at §488.7(d).
- ++ Assess the Joint Commission's ability to report deficiencies to the surveyed facility and respond to the facility's plan of correction in a timely manner.
- ++ Establish the Joint Commission's ability to provide us with electronic data and reports in requested format necessary for effective validation and assessment of the Joint Commission's survey process.
- ++ Review the Joint Commission's ability to provide adequate funding for performing required surveys.
- ++ Confirm the Joint Commission's policies with respect to whether surveys are announced or unannounced.
- ++ Obtain the Joint Commission's agreement to provide us with a copy of the most recent accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the October 25, 2013 proposed notice (78 FR 63984) also solicited public comments regarding whether the Joint Commission's

requirements meet or exceed the Medicare conditions of participation for HHAs. We received no public comments in response to our proposed notice.

IV. Provisions of the Final Notice

A. <u>Differences Between the Joint Commission's Standards and Requirements for Accreditation</u> and Medicare's Conditions and Survey Requirements

We compared the standards contained in the Joint Commission's Medicare program accreditation requirements for HHAs and its survey process in the Joint Commission's Application for Renewal of Deeming Authority for HHA Facilities with the Medicare HHA conditions for participation and our State Operations Manual. Our review and evaluation of the Joint Commission's accreditation application, which were conducted as described in section III. of this final notice, yielded the following:

- To meet the requirements at §484.2, the Joint Commission revised its glossary to include all HHA definitions.
- To meet the requirements at §484.4(a)(1), the Joint Commission revised it's glossary to include the required qualifications for an Occupational Therapist and Occupational Therapy assistant.
- To meet the requirements at §484.4, the Joint Commission revised it's glossary to include the required qualifications for a Physical Therapist and Physical Therapy Assistant.
- To meet the requirements at §484.10, the Joint Commission revised its standards to address the requirement that the HHA protect and promote the exercise of a patient's rights.
- To meet the requirements at §484.10(b)(5), the Joint Commission revised its standards to address the requirement that the HHA "must" investigate complaints.
- To meet the requirements at §484.10(d), the Joint Commission modified its standards to ensure the patient's right to confidentiality of the medical record.
 - To meet the requirements at §484.10(f), the Joint Commission revised its standards to

address the patient's right to use the HHA hotline to lodge complaints concerning the implementation of the advance directives requirements.

- To meet the requirements at §484.36(c)(1), the Joint Commission revised its policies and procedures to ensure patient care instructions provided to the home health aide are clearly written and do not include the use of visit ranges and other assignments at the discretion of the aide.
- To meet the requirements at §484.14(b), the Joint Commission revised its standards to address the governing body's responsibility to adopt and periodically review written bylaws or an acceptable equivalent and oversee fiscal affairs.
- To meet the requirements at §484.16, the Joint Commission modified its standards to require that the group of professional personnel establish and annually review policies governing medical supervision, plans of care, and personnel qualifications.
- To meet the requirements at §484.18, the Joint Commission revised its standards to require the plan of care be established by a doctor of medicine, osteopathy, or podiatric medicine.
- To meet the requirements at §484.18(c), the Joint Commission revised its standards to require "an assessment for contraindications" be conducted prior to administration of drugs and treatment.
- To meet the requirements at §484.32(a), the Joint Commission revised its standards to address the requirement that a physical therapy assistant or occupational therapy assistant can perform services planned, delegated, and supervised by the therapist.
- To meet the requirements at §484.36, the Joint Commission modified its standards to ensure the home health aide's competence in providing care.
- To meet the requirements at §484.36(a)(2)(i)(B), the Joint Commission revised its standards to include a reference to the personnel qualifications at §484.4.

- To meet the requirements at §484.38, the Joint Commission revised its standards to address the additional health and safety requirements set forth in §485.711, §485.713, §485.715, §485.719, §485.723, and §485.727 of the Code of Federal Regulations (CFR) to implement section 1861(p) of the Act.
- To meet the requirements at §484.48(b), the Joint Commission revised its standards to ensure clinical record information is "safeguarded against loss."
- To meet the requirements at §484.52, the Joint Commission revised its standards to ensure the HHA's required annual self-evaluation assess the extent to which the agency's program is appropriate, adequate, effective and efficient.
- To meet the requirements at §484.52(b), the Joint Commission revised its standards to ensure the HHA include appropriate health professionals that represent "the scope of the program" in the required quarterly internal HHA review of a sample of clinical records.
- To meet the requirements at §488.4(b)(3)(iii) and §488.8(d)(1), the Joint Commission revised its policies to ensure that CMS is notified in advance of any proposed changes in its approved Medicare HHA accreditation program.
- To meet the requirements of the Joint Commission's Appendix L "Addendum for Home Health Deemed Status Surveys", the Joint Commission modified its policy to ensure surveyors conduct the required number of case reviews that include observing home visits.
- The Joint Commission amended its policy to clearly state that follow-up surveys following identification of condition-level non-compliance are conducted within 45 "calendar" days of the survey end date.
- During the review of the Joint Commission's application, CMS issued notice to the Joint Commission with respect to all of its CMS-approved Medicare accreditation programs, in connection with its citation practices and its use of standards that are frequency-based and require a minimum frequency of observations of deficient practices before a citation will be

made, so-called "C- weighted" standards. Due to the fact that this letter was released late in the review of the Joint Commission's current HHA application, there was not sufficient time for the Joint Commission to fully implement and provide evidence of sustained compliance with the provisions of this notice. To verify compliance in this area, CMS will conduct a follow-up survey observation and corporate onsite within one year of the date of publication of this notice.

B. Term of Approval

Based on the review and observations described in section III. of this final notice, we have determined that the Joint Commission's requirements for HHAs meet or exceed our requirements. Therefore, we approve the Joint Commission as a national accreditation organization for HHAs that request participation in the Medicare program, effective March 31, 2014 through March 31, 2020.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

	Marilyn Tavenner,	

Administrator,

Centers for Medicare & Medicaid Services.

BILLING CODE: 4120-01-P

[FR Doc. 2014-05328 Filed 03/11/2014 at 8:45 am; Publication Date: 03/12/2014]